HUMAN RESEARCH ETHICS PROGRAM
NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES
www.nj.gov/health/hrep

ASSURANCE FOR THE ETHICAL CONDUCT OF RESEARCH

Introduction:
The conduct of human research within or related to the mission of the New Jersey Department of Health and Senior Services ("Department") requires investigators and research-related personnel to meet critical ethical and regulatory obligations. These obligations fulfill requirements arising from the Federal Wide Assurance (FWA00004020) granted to the Department by the Office for Human Research Protections, U.S. Department of Health and Human Services. Such ethical and regulatory responsibilities are articulated in The Belmont Report, 45 CFR 46, federal human research-related laws and regulations, state laws and regulations, and Department specific policies. To meet the Department's responsibilities in human research, investigators and key personnel must be informed of the requirements and agree to abide by these obligations in writing. This document certifies that this process of information and commitment has taken place. The responsibilities are indicated below. Your signature at the conclusion indicates your free commitment to abide by all ethical principles and regulations to protect the rights and welfare of human research participants. Your signature further indicates your accepting responsibility that investigators and other staff who participate on this project with or under you will do the same.

Responsibilities to Research Subjects:
As a member of the research team for the specified project, I will safeguard at all times the ethical rights and welfare of research subjects by placing their interests above all other considerations, including the goals of the research as well as my personal and professional concerns. I freely assume responsibility for protecting the privacy of research subjects, obtaining consent/assent in a manner that demonstrates a respect for persons, and only implementing recruitment methods grounded in justice and beneficence. To ensure I fulfill these responsibilities I have read The Belmont Report, and I have fulfilled and completed my institution's required research ethics educational standards and programs.

Responsibilities to the Department and Institutional Review Board:
As a member of the research team for the specified project, I will ensure that all research activities are accomplished in accordance with The Belmont Report, 45 CFR 46, Federal laws and regulations, New Jersey laws and regulations, Department policies, and all Department and Institutional Review Board (IRB) decisions, determinations and requirements. I will ensure IRB approval is obtained prior to performing or modifying research activities, except when implementing a modification that would mitigate an immediate harm to research subjects. I will fully cooperate with Department or IRB site-visits, audits, investigations and inquiries, providing access to all records, documents and data, in all forms. I will fully cooperate with the IRB in fulfillment of its responsibilities for the initial and continuing review of the project specified below, providing information as directed. I will promptly notify the IRB if research is implemented or modified without prior IRB approval, if research violates IRB requirements, or if there is a serious unanticipated adverse event to a research subject or an unanticipated problem involving risks to subjects or others.

I certify that I understand and accept these responsibilities for the ethical protection of research subjects.

Research Project Title: _____

Name: _____ Role in Research Project: _____

Signature: _____ Date: _____